

Health consequences of vasectomy in India*

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Vasectomy acceptance has been declining in India during the past 20 years. Even if the risk of prostate cancer is marginally higher in vasectomized men, this risk in India has to be assessed against the immediate safety and other possible long-term benefits of this procedure. The Indian Council of Medical Research has launched a case-control study, which is unlikely to be time-consuming or beyond the available means and resources, in order to obtain definitive data on this problem. Meanwhile, vasectomy remains an excellent procedure for the couple seeking permanent methods of contraception, and specific efforts to promote its acceptance must continue in India.

The article on the safety of vasectomy by Farley et al. (1) and the subsequent communication by Wildschut & Moninckx (2) considered the need for studies to explore a possible association between prostate cancer and vasectomy in developing countries like India. This question is discussed below in the context of current research efforts of the Indian Council of Medical Research in this area.

Prevalence and acceptance

Although Farley et al. and Wildschut & Moninckx stated that vasectomy is widely practised in India, the estimated prevalence of vasectomy is only 7%. Several developed countries (Australia, New Zealand, United Kingdom and the USA) and at least one developing country (Republic of Korea) have higher prevalences of vasectomy. However, by virtue of the size of the population, China and India have the largest number of vasectomized men in the world.

Contrary to the global trend there has been a progressive decline in vasectomy acceptance in India during the last twenty years; in 1992 it accounted for only 4.2% of all sterilizations (Table 1) (3). It has been suggested that bottlenecks in the organizational structure and poor access to services might be the

major factors responsible for the observed decline in vasectomies. Currently the government of India is taking necessary steps to correct these bottlenecks, popularize vasectomy and persuade men to participate in the planned parenthood movement through acceptance of this simple and safe procedure.

Long-term consequences

The Indian Council of Medical Research (ICMR) continuously reviews the global data on the safety of all contraceptive methods. In 1993 a review of the global data on the long-term health consequences of vasectomy and the implications of the findings to the Indian population was carried out (overview communicated to the *Indian journal of medical research*). The data were presented to the Scientific Advisory Groups (SAG) of the Divisions of Human Resource Development Research and Non-Communicable Diseases of the ICMR.

Table 1: Changing trends in vasectomy in India^a

Year	No. of sterilizations	No. of vasectomies	Vasectomy (%)
1960	64 338	37 596	58.4
1970	1 422 110	1 055 860	74.2
1980	1 777 924	472 687	26.6
1990	4 181 322	341 256	8.2
1991	4 125 555	254 905	6.2
1992 ^b	4 089 178	174 008	4.2

^a Source: Ref. 3.

^b Figures for 1992: provisional unpublished data, Ministry of Health and Family Welfare, New Delhi.

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The Advisory Groups noted that:

(1) There is no unanimity even among the investigators from the same country (USA) about the elevated risk of prostate cancer among vasectomized men; even if an association exists it is weak and could be due to methodological errors. In the Indian context where the incidence of prostate cancer is low (1.9–7.2 per 100 000) (3), the risk might be higher, lower or with no association.

(2) Results from most of the studies indicate that the overall morbidity and mortality rates due to malignancies in men who had undergone vasectomy are essentially similar to or lower than the rates in the controls drawn from the same community. India has one of the lowest incidence rates of malignancies in the world and prostate cancer is rare (4). In view of these differences it is necessary to find out whether any association between vasectomy and malignancies in general, and prostate cancer in particular, exist in the Indian population and, if so, the magnitude and the direction of the association.

(3) Several investigators from both technically advanced and developing countries have reported that the risk of cardiovascular diseases and cerebrovascular diseases in vasectomized men is lower. There are, however, conflicting time-trends found in the same study and differences between studies in the same country; these might be due to the fact that the reported lower CVD risk is mediated mainly through the profile and lifestyles of the vasectomy acceptors and are not due to consequences of the procedure *per se*. In India vasectomized persons are unlikely to differ from the general population in terms of lifestyles.

(4) The prevalence of cardiovascular diseases is high in India and prevalence rates continue to rise (5). Indians settled in the United Kingdom and USA have a higher prevalence of cardiovascular diseases than the Caucasian citizens (6). So far, no studies exploring an association, if any, between vasectomy and cardiovascular or cerebrovascular diseases have been carried out in India. It is essential to ascertain whether the protective effect of vasectomy is applicable to the Indian population and, if so, the magnitude of such an effect.

Retrospective studies

A proposal by the World Health Organization that the ICMR should participate in a WHO multi-country study on prostate cancer has been approved by the SAG, the ICMR Ethical Committee, and the Health Ministry Screening Committee.

The SAG recommended that the ICMR should, in addition, concurrently take up a comprehensive

study to assess the risk of cardiovascular disease, cerebrovascular accidents, and cancers other than prostate cancer so that all the long-term risks and benefits associated with vasectomy in India could be weighed against its well-known short-term safety, and a balanced conclusion in the Indian context could be drawn. The SAG suggested that a case-control study should be started immediately and completed expeditiously because the majority of vasectomized men in India will be over fifty years of age in the 1990s.

The ICMR therefore drew up a protocol for a multicentre case-control study to investigate the association between vasectomy and cancer, cardiovascular and cerebrovascular disease in men aged 50 years or above who had undergone vasectomy at least ten years earlier, and obtained the necessary clearances from the SAG and the Ethical Committee. The pilot phase to assess the feasibility and pre-test the protocol of the study has been completed and the main study has started. Part of the study dealing with the assessment of risk of prostate cancer and vasectomy is likely to be taken up in collaboration with WHO; the rest is being funded by ICMR. It is expected that in about two years this study will provide data on the risks and benefits associated with vasectomy in India so that a balanced assessment of the long-term consequences could be presented to policy-makers, physicians and potential clients. All these are deliberate steps and actions initiated to obtain necessary information.

Discussion

The statement by Wildschut & Monincx about undue anxiety in India does not appear to be warranted (2). These authors used data on the incidence of prostate cancer, which was reported by the National Cancer Registry Programme of the ICMR (4), to argue that, from the epidemiological point of view, there is no need for time-consuming and expensive studies in developing countries like India to detect a possible link between vasectomy and prostate cancer. Their reasons were that these studies would not add to what we know already and that, even with a strong association between vasectomy and subsequent cancer of the prostate, the potential public health impact would be small because of the low incidence of prostate cancer in developing countries.

However, in the present decade, India is expected to show a substantial increase in the proportion and number of individuals above 50 years of age. The prevalence of all malignancies including cancer of the prostate (as well as cardiovascular diseases) is higher in this age group so that clinicians will be

seeing more cancer cases, including cancer of the prostate even if the incidence of the disease remains unaltered. Moreover, the majority of the 13 million Indians who had undergone vasectomy did so prior to 1977 and will in the 1990s be 50 years or older, the age group with a higher prevalence of prostate cancer.

Clinicians, who are concerned about a possible association between cancer of the prostate and vasectomy will probably find that some of their patients with prostate cancer had undergone vasectomy; because of the rarity of the cancer, they will not be able to assess whether vasectomized men in India are at higher risk of this cancer. Thus, a situation is likely to arise in the near future when physicians, the public and health policy-makers will demand that the vital epidemiological information on the relative risk of prostate cancer in vasectomized men in India should be available, so that they could make informed choices.

The main concern is not that vasectomy may lead to a rise in the incidence of prostate cancer, but that in the absence of valid data on the risk of prostate cancer in vasectomized men in India, the decline in vasectomy acceptance may accelerate. It is unlikely that health policy planners and the public will be satisfied with the argument that as the potential public health impact of the increased risk, if any, is small, the country need not spend resources to obtain this information.

The public's reaction to the health hazards associated with contraception is often out of proportion to the magnitude of the risk and in some instances occurs even in the absence of such a risk. For example, there was a steep fall in the use of low-dose oral contraceptives (OC) in the United Kingdom following publication about a higher risk of breast cancer in a small subsegment of high-dose OC users. Also, the use of IUDs in the USA is low even now, more than a decade after the reports of adverse health consequences from just one type of IUD (Dalcon Shield) although the current IUDs are without this problem. As contraceptives are used by healthy individuals for long periods of time, it is reasonable for men and women to prefer to be on the side of safety. It is therefore essential that correct information on the relative risk of prostate cancer in vasectomized individuals be published and made available to the potential client so that he can make an informed choice based on Indian data.

India has a vast network of hospitals and well-trained, committed clinicians. The ICMR has for many years successfully conducted clinical research through this network, with minimal additional funding. Pilot studies carried out by the ICMR indicate that it will be possible to complete the case-control

study on the long-term consequences of vasectomy within two years using the existing resources. Thus, the study in India is unlikely to be a time-consuming and expensive exercise.

Wildschut & Moninckx (2) also raised two other issues:

- should vasectomy be temporarily discouraged until further scientific evidence shows that the association between vasectomy and prostate cancer is false?
- what happens to future family planning programmes if the new studies support the earlier findings?

The ideal contraceptive — totally free of risks — does not exist and is unlikely to be discovered in the near future. Even if the risk of prostate cancer is marginally higher in vasectomized men, this risk in India has to be assessed against the immediate safety and possible long-term protection against cardiovascular diseases. Current research efforts of the ICMR seek to obtain and provide data on this problem in the context of an overall balance of risks and benefits — both immediate and delayed.

In India, most couples complete their families by the time they are in their mid-twenties. Families are stable and divorces and remarriages are not common. In this situation, terminal methods of contraception which are safe, effective and not associated with long-term health hazards are the right choice for these young couples who require freedom from pregnancy for the next 25 years.

In view of its immediate safety, low cost and feasibility in the primary health care set-up, vasectomy remains an eminently suitable procedure for the couple seeking permanent methods of contraception. Therefore, in India, specific efforts to popularize vasectomy will have to continue.

Résumé

Inde: Conséquences de la vasectomie pour la santé

En Inde, l'acceptation de la vasectomie est allée en diminuant au cours des vingt dernières années. Même si le risque de cancer de la prostate est très légèrement plus élevé chez les hommes vasectomisés, en Inde il faut évaluer ce risque par rapport à la sécurité immédiate et aux autres avantages éventuels à long terme qu'offre cette méthode. L'Indian Council of Medical Research a lancé une étude cas-témoins qui ne devrait pas prendre trop de temps ni demander des moyens et des ressources exceptionnels, de façon à obte-

nir des données définitives sur la question. En attendant, la vasectomie reste une excellente méthode pour les couples qui recherchent une contraception permanente et les efforts visant à promouvoir son acceptation doivent se poursuivre en Inde.

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